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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,838	04/10/97	GAYNOR B	96700/451

HM22/0620
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EXAMINER	
EWOLDT,G	
ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 06/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/833,838	Applicant(s) Gaynor et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Mar 27, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *45-53* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *45-53* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply With Sequence Requirement

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644.

2. Applicant's Amendment, filed 3/27/00, is acknowledged.

3. Applicant's election without traverse of Group VII, claims 45-53, in Paper No. 7 is acknowledged.
Claims 45-53 are pending.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, the sequences on pages 3-4, 6-7, 13, and 15-20, and Tables 2 and 3 of the specification, and the sequences in Figures 2-4 must be brought into sequence rule compliance.

5. Substitute Tables 2 and 3 are required that include SEQ ID NOS: identifying all the listed sequences.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 45-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "a method for treating systemic lupus erythematosus (SLE) associated glomerulonephritis" by administering peptides:

A) d-DWEYS,
B) XGWXRV (SEQ ID NO:2),
C) XWXYHX (SEQ ID NO:3),
D) (D/E)G(D/E)WPR (SEQ ID NO:5), or
E) (D/E)W(D/E)Y(G/S) (SEQ ID NO:4),

does not reasonably provide enablement for "a method for treating or preventing any glomerulonephritis" by administering peptides:

A) which bind an anti-doublestranded (αds)-DNA antibody (claims 45 and 51),
B) comprising D-amino acids (claims 46 and 52).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to:

A) the treating of all glomerulonephritis,
B) the preventing of any glomerulonephritis,
C) the peptides of claims 45-46 and 51-52.

The Merck Manual (1999) teaches that glomerulonephritis can be associated with bacterial, viral, fungal, and parasitic infections as well as with SLE (in particular, Table 224-2, page 1859). Only SLE associated glomerulonephritis is thought to be mediated by anti-doublestranded (αds)-DNA antibodies (in particular, Table 224-4, page 1861). One skilled in the art would therefore conclude that the claimed method of binding αds-DNA antibodies with peptides specific for said antibodies would not provide an effective treatment for glomerulonephritis associated with different antigens, i.e., glomerulonephritis not associated with (αds)-DNA antibodies. Additionally, examples C. and D. (Page 17-18) disclose that the results of *in vitro* and *in vivo* peptide binding experiments are unpredictable. While the L-DWEYS peptide appears to compete better for the binding of glomerulonephritis αds-DNA antibodies *in vitro* (example C.) (and would thus be thought to provide a more effective treatment), the d-DWEYS peptide appears to bind said antibodies better *in vivo* (example D.) (and thus the d-peptide appears to actually provide a more effective treatment). Also, the specification provides insufficient evidence that any type of glomerulonephritis can be prevented. As neither peptide disclosed in example D. *prevented* the binding of αds-DNA antibodies to renal tissue *in vivo*, neither peptide could be assumed to *prevent* glomerulonephritis. Claims 45-46 and 51-52 recite *any* and/or *all* D-amino acids while only a single example is disclosed. Given the disclosure that a single amino acid change between antibodies 95 and R4A causes the complete abrogation of binding of ds-DNA by antibody 95 (page 18, lines 27-29), one skilled in the art would conclude that the reverse could also be true, i.e., even single amino acid changes in the peptide amino acid sequence could also cause grossly different binding characteristics of the peptides. Janeway et al. (1994) teach that a single amino acid difference between a chicken protein and its turkey homolog completely abrogates binding of an antibody to the turkey protein (page 3-14).

In view of the quantity of experimentation necessary, the lack of relevant working examples (especially concerning glomerulonephritis not associated with SLE and αds-DNA antibodies), the lack of guidance as to how to identify αds-DNA antibody binding peptides, the unpredictability of the art as demonstrated by Applicant's examples, and the breadth of the claims including the prevention of glomerulonephritis, it would take undue trials and errors to practice the claimed invention.

8. Claims 45-46 and 51-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that, other than the peptides d-DWEYS, XGWXRV (SEQ ID NO:2), XWXYHX (SEQ ID NO:3), (D/E)G(D/E)WPR (SEQ ID NO:5), and (D/E)W(D/E)Y(G/S) (SEQ ID NO:4), Applicant was in possession of peptides for treating or preventing glomerulonephritis. Claims 45-46 and 51-52 recite an unlimited number of L and D-amino acid peptides. The open language and lack of limitations would therefore include thousands of peptides for which no αds-DNA antibody-binding activity has been established. Additionally, the specification fails to give sufficient direction for how to establish αds-DNA antibody-binding activity, other than to test any given peptide experimentally. While some speculation as to possible peptide binding characteristics is offered on pages 18-21, even those guidelines are contradicted by the binding of peptides such as Φ1-1, Φ7-6, and B-21 (Tables 2 and 3). One of skill in the art would therefore conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

9. The instant claims may not have the benefit under 35 U.S.C. § 120 of the parent filing date, 9/20/95. Subject matter claimed in the instant application is not supported in the parent application, Serial Number 08/331,832. Specifically, the parent application does not disclose "a method for treating or preventing glomerulonephritis" (Claims 45-53).

If applicants disagree, applicants should present a detailed analysis as to why the claimed subject matter has clear support in the parent applications.

The filing date of the instant claims is deemed to be the filing date of the instant application, i.e. 4/10/97.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 45-46 and 49-53 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Gaynor et al. (March, 1997).

Gaynor et al. teach a method for treating glomerulonephritis comprising the administration of the αds-DNA antibody-binding peptides, d-DWEYS, (D/E)G(D/E)WPR (SEQ ID NO:5), and/or (D/E)W(D/E)Y(G/S) (SEQ ID NO:4) to a subject, (see particularly page 1956, column 2 paragraphs 3-4; page 1958, column 1, paragraph 2, page 1960, column 1 paragraph 2).

The reference teaching clearly anticipates the claimed invention.

12. Claims 45, 49, 51, and 53 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Spatz et al. (January, 1997).

Spatz et al. teach a method for treating renal failure (glomerulonephritis) mediated by αds-DNA antibodies comprising the administration of the αds-DNA antibody-binding peptide, (D/E)W(D/E)Y(G/S) (SEQ ID NO:4) and other peptides to a subject, (see particularly page 70, column 2 paragraph 1 and page 73, column 1, last paragraph - column 2, first paragraph).

The reference teaching clearly anticipates the claimed invention.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 45-46 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spatz et al.

Spatz et al. has been discussed supra.

The reference differs from the claimed invention in that it does not teach a method for treating renal failure (glomerulonephritis) mediated by αds-DNA antibodies comprising the administration of D-amino acid αds-DNA antibody-binding peptides. However, the L and D isomers are obvious variations of one another, absent a showing of unobvious properties. Further, it is well established that with regard to chemical compounds a close similarity of chemical structure may be sufficient to establish a *prima facie* case of obviousness which arises from the expectation that compounds of similar structure will have similar properties. See *In re* Payne, 606 F.2d 303,203 USPQ 245,254 (CCPA 1979), *In re* Gyurik, 596 F.2d 1012,201 USPQ 553,557 (CCPA 1979), *In re* Hoch, 428 F.2d 1341,166 USPQ 406,409 (CCPA 1970).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for treating renal failure (glomerulonephritis) mediated by αds-DNA antibodies using the D isomer peptides instead of the L isomer peptides, as taught by Spatz et al. One of ordinary skill in the art at the time the invention was made would have been motivated to perform said method using D isomers because said D isomers are obvious variations of the peptides, absent a showing of unobvious properties. Further, it is well established that with regard to chemical compounds a close similarity of chemical structure may be sufficient to establish a *prima facie* case of obviousness which arises from the expectation that compounds of similar structure will have similar properties. See *In re* Payne, 606 F.2d 303,203 USPQ 245,254 (CCPA 1979), *In re* Gyurik, 596 F.2d 1012,201 USPQ 553,557 (CCPA 1979), *In re* Hoch, 428 F.2d 1341,166 USPQ 406,409 (CCPA 1970).

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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June 16, 2000

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